Section 05 – 510(k) Summary

K124685

MAR 1 2 2013

This Summary of Safety and Effectiveness is submitted in accordance with 21 CFR 807.92.c.

1 – Administrative Information

1- a. Type of 510(k) submission:

These documents constitute a Traditional 510(k) Submission.

1- b. Submission date: June 1, 2012

1-c. 510(k) Submitter:

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1- è. Establishment registration number: 9615782

Section 05 – 510(k) Summary

2 – Device Information

2-a. Common Name of device:	Laser fluorescence caries detection device
2-b. Trade Name of device:	SOPROCARE
2-c. Classification regulation:	21 CFR 872.1745
2-d. Medical Device Class:	II
2-e. Panel:	Dental
2-f. Product code:	NBL
2-g Subsequent Product Codes	NYH, EIX

3 – Identification of legally marketed device(s)

The Substantial Equivalence (SE) of the New Device is based on the Predicates Devices identified in the Table 01.

Table 01 – Identification of legally marketed devices

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
SOPROLIFE	SOPRO	NBL	K092583	January 13, 2010
GC Tri Plaque ID Gel	GC CORPS	NYH	Not required	NA
PROBE, PERIODONTIC	AESCULAP AG	EIX	Exempted	NA

SOPRO SOPROLIFE (K092583) device is used as Predicate for pit and fissure caries and intra-oral camera claims for the New Device.

GC CORPS Tri Plaque ID Gel (510K not required) is used as Predicate for dental plaque highlight claims for the New Device.

AESCULAP AG PROBE (510K Exempted) is used as Predicate for gingival inflammations highlight claims for the New Device (restricted to gingival inflammations which lead to bleeding upon probing).

Section 05 – 510(k) Summary

4 – Description of the Device

The New Device is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).

It provides the following benefits:

- Aids in the detection of pit and fissure caries
- Information about patient dental hygiene
- Highlight dental plaque
- Highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing)
- Show the difference between "before" and "after" care (follow-up).

In CARIO mode (blue mode), the camera helps the dental practitioner to highlight carious warning on pits and fissures of the occlusal side of the teeth.

In DAYLIGHT mode (white mode), the camera enables to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).

In PERIO mode (yellow mode), the camera helps the dental practitioner to see the presence of dental plaque but also to highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing). This mode offers the dentist and/or hygienist a tool for improved communication, motivation and education of his/her patients, who will then become aware of their oral health condition.

The New Device is an intra-oral video camera equipped with LEDs to light the inspection site. Thanks to its technology based on fluorescence phenomenon (given by its LED lamps) and chromatic amplification, this camera will permit a global care of the patient. The optics and the charge coupled device (CCD) sensor in the New Device picks up the images containing this fluorescence highlight site and converts them to a video signal that is sent to a video monitor or computer monitor. Dental practitioner and/or hygienist, as an aid for diagnosis, can use the results of this image.

The handpiece can be connected with different SOPRO docking station such as: DOCK M_USB2, DOCK MU_USB2, DOCK USB2…..

TABLE 2

Main Design Characteristics of New Device

Light Source	4 LEDs White 3 LEDs Blue
Wavelength (blue led) excitation signal	450nm
Returned light	Standard image and Fluorescence
CCD	¼" High sensitivity
Resolution	752 x 582 PAL 768 x 494 NTSC
Definition	470 lines
Sensitivity	2 lux
Adjustment	4 presets positions : *Extra oral* *Intra oral* *Care = fluorescence mode* *Macro*
System of image capture	Image capture through SoproTouch or footswitch (optional)
Angle of view	70°
Cable length	2,5 m
Hand piece dimension	L = 200 mm x W = 28 mm x H = 24 mm
Hand piece weight	78g
Working temperature	10 -40°C (50-104°F)
Power supply	Depending docking station
User interface	LCD Screen or Computer

5 – Intended Use

The New Device is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).

Section 05 – 510(k) Summary

6 – Technological characteristics of the New Device compared to the Predicates Devices

6.1 Technological characteristics of the New Device compared to the Predicate Device for pit and fissure caries detection and intra-oral camera.

The Predicate Device is SOPROLIFE (K092583, January 13, 2010)

Technological perspective:
The New Device and the Predicate Device use the same technology (CCD sensor, Blue and white LEDs) and the same technical concept (fluorescence phenomenon).

Material perspective:
The New Device and the Predicate Device are extremely similar because they both share the same external housing (shape and material, only color is different).

Design perspective:
The New Device and the Predicate Device use the same:

- Electronic board (except led board).
- External Housing (except shape color).
- Optical design.
- Accessories.

Energy source perspective:
The New Device and the Predicate Device:

- Use the same input energy source (electric power supply).
- Deliver the same output energy source (light emission).

Material in contact with the patient:
Because the New Device and the Predicate Device use the same tips and protection sheath, the materials in contact with the patient are the same.

Displayed image for aid to pit and fissure caries detection
The New Device and the Predicate Device:

- Use an anatomic view of the tooth
- Highlight the suspicious pit and fissure caries in red

The Predicate Device displays healthy dentine fluorescence in green.
The New Device displays the area outside pit and fissure caries in black and white.

6.2 Technological characteristics of the New Device compared to the Predicate Device for highlight dental plaque.

The Predicate Device is GC Tri Plaque ID Gel (510k exempt)

Technological perspective:
The New Device uses a different technology (CCD sensor, Blue and white LEDs) compared to a chemical solution. The New Device uses fluorescence of bacteria present in dental plaque whereas Predicate Device is a coloration of dental plaque.

Material perspective:
The New Device is made with plastic and electronic.
The Predicate Device is a solution that needs to be applied everywhere in the patient's mouth.

Design perspective:
The New Device is made up of plastic and electronic.
The Predicate Device is a solution that needs to be applied everywhere in the patient's mouth.

Energy source perspective:
The New Device uses electric power supply.
The Predicate Device does not require energy source.

Material in contact with the patient:
The New Device materials in contact with the patient are the tips and protection sheath, the contact is quite brief and punctual.
The Predicate Device needs to be applied everywhere in the mouth and coloration remains several hours after examination.

Section 05 – 510(k) Summary

6.3 Technological characteristics of the New Device compared to the Predicate Device for highlighting gingival inflammations (restricted to gingival inflammations, which lead to bleeding upon probing)

The Predicate Device is AESCULAP AG Periodontic probe (510k Exempt)

The gingival inflammation is mainly detected by a visual inspection of the gum, if a more effective diagnosis is to be placed, practitioner can use a more invasive technique: bleeding upon probing test.

Technological perspective:
The New Device uses a different technology, chromatic amplification (using CCD sensor, Blue and white LEDs) compared to bleeding upon probing (which is a visual inspection of site after probing).

Material perspective:
The New Device is made with plastic and electronic.
Other cited techniques use human eye and a probe.

Design perspective:
The New Device is made with plastic and electronic.
Other cited techniques use human eye and a probe.

Energy source perspective:
The New Device uses electric power supply.
Other cited techniques don't require energy source.

Material in contact with the patient:
The New Device materials in contact are the tips and protection sheath, the contact is quite brief and punctual.
For bleeding after probing techniques, the probe is firmly pressed in the gum in several areas.

Section 05 – 510(k) Summary

7 – Determination of substantial equivalence

The New Device is an intra-oral video camera equipped with LEDs to light the inspection site. The Predicate Device SOPROLIFE is the same kind of device. Indications for use are similar for pit and fissure caries.
The New Device is the same as the Soprolife (K092583, January 13, 2010) Predicate Device in terms of functioning principle. Both devices use the fluorescence phenomenon. Also the Devices use the same housing, dental barrier and the same tips.
From internal structure perspective, Devices are extremely similar, all components used are the same for the New Device and the Predicate Device (with exception of the led board).
From external structure perspective, the devices are extremely similar because the casings are made in self-extinguishing material (UL94-V0) only color of housing has changed.
Moreover, the materials in contact with the patient are exactly the same.

Regarding dental plaque highlight, New Device and Predicate Device (GC Tri Plaque ID Gel) have the same intended use. The technology is different but the new characteristics do not affect safety or effectiveness.

Regarding gingival inflammations highlight (restricted to gingival inflammations which lead to bleeding upon probing), New Device and Predicate Device (Periodontic probe) have the same intended use. The technology is different but the new characteristics don't affect safety or effectiveness.

Discussion of the non-clinical Tests:

The aim of the evaluation was to demonstrate the Substantial Equivalence between New Device and the selected Predicate Device SOPROLIFE in terms of Performances.

The evaluated Performances were:
- Image focus position
- Image luminosity
- Led illumination

After tests, the obtained results for the New Device have been directly compared to the Predicate Device Performances. The results of the comparison show that the Performances of the New Device and the Predicate Device are similar.

Discussion of the safety Tests:

From a safety point of view:
The device has been tested to the following standards:

The Electromagnetic Compatibility has been performed according to:

- AAMI / ANSI / IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). (General) (Recognition Number: 5-54).

The Electrical Safety has been performed according to:

- The IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. (Dental/ENT) Recognition Number 4-187

Discussion about clinical data:

Clinical data has been collected during the following study:

"Diagnosis aid capabilities of Soprocare camera"
January 6 to February 7 2012 at Marseille

Definition: In medicine and statistics, gold standard test refers to a diagnostic test or benchmark that is the best available under reasonable conditions. The gold standard is the reference and it is supposed to never be wrong and so have sensitivity and specificity of 100%.

The aims of this study were to determine if:

- New Device has a comparable effectiveness as Predicate Device SOPROLIFE (used as gold standard for pit and fissure caries detection).
- New Device has a comparable effectiveness as GC Tri Plaque ID Gel Predicate Device (used as gold standard for dental plaque highlight).
- New Device has a comparable effectiveness as bleeding upon probing technique (used as gold standard) regarding gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing).
- New Device would improve diagnosis capability compared to practitioner using only visual inspection

20 people have been enrolled in this study (9 women and 11 men) aged from 20 to 41 years.

- A total of 120 teeth have been studied for dental plaque and inflammation analysis
- A total of 128 teeth have been studied for pit and fissure caries detection

In terms of safety the study did not show any particular risk associated with New Device, it showed same safety as Predicates Devices. No adverse events or complications occurred.

Section 05 – 510(k) Summary

During this study, New Device has demonstrated its effectiveness by achieving:

- High accuracy (87 % in average) : capacity to get the same results as the gold standard
- High Sensitivity (91 % in average) : capacity to highlight a trouble detected by the gold standard
- High specificity (90 % in average) : capacity to confirm the absence of a trouble stated by the gold standard

The practitioner eyes achieved:

- Moderate accuracy (66 % in average) : capacity to get the same results as the gold standard
- Low Sensitivity (25 % in average) : capacity to highlight a trouble detected by the gold standard
- High specificity (97 % in average) : capacity to confirm the absence of a trouble stated by the gold standard

8 – Conclusion

The New Device is the same as the SOPROLIFE identified Predicate Device in terms of indication for use for aid to pit and fissure caries detection.
Because of the used technologies, characteristics and performances are similar to the Predicate Device; the characteristics of the SOPROCARE do not affect the Safety of the patients or of the operator. Moreover, the Effectiveness is the same as of the Predicate Device.

The New Device is the same as the GC Tri Plaque ID Gel identified Predicate Device in terms of indication for use for dental plaque highlight. Even though technology used is different, it doesn't affect safety and effectiveness as confirmed by performance data provided.

The New Device is the same as the periodontic probe identified Predicate Device in terms of indication for use for gingival inflammations highlight (restricted to gingival inflammations which lead to bleeding upon probing). Even though technology used is different, it doesn't affect safety and effectiveness as confirmed by performance data provided.

The New Device is as safe and effective as the predicates for the intended uses.

The New Device is substantially equivalent to the SOPROLIFE Predicate Device (K092583, January 13, 2010) as an aid to pit and fissure caries detection.
The New Device is substantially equivalent to GC Tri Plaque ID Gel Predicate Device as an aid to highlight dental plaque.
The New Device is substantially equivalent to periodontic probe Predicate Device as an aid to highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

SOPRO Acteongroup
C/O Mr. Rick Rosati
Quality Manager
Acteon, Incorporated
124 Gaither Drive, Suite 140
MOUNT LAUREL NJ 08054

Re: K121685
Trade/Device Name: SOPROCARE
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL, NYH
Dated: February 14, 2013
Received: February 21, 2013

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04 – Indication for Use

Indications for Use

510(k) Number (if known): K121685

Device Name: SOPROCARE

Indications for Use:

The New Device is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.03.11
15:30:11 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121685